

## **REMARKS**

Reconsideration of this application, as amended, is respectfully requested.

### **I. Specification amendments**

The specification at pages 14 and 17 were amended to reflect the new ATCC location and to capitalize trademarks, respectively. No new matter has been added to the application as a result of this amendment.

### **II. Status of the claims**

Claims 1-29, 67-79, 94-103, and 105-124 were pending in this case. Claims 4, 5, and 13-15 were withdrawn as being directed to non-elected inventions. Claims 78, 94-121 and 105-121 were cancelled without prejudice or disclaimer. Claims 1-29, 67-77, and 79 are now pending in this application. No new matter has been introduced into the amendment.

The finality of the restriction requirement and election of species is duly noted. Applicants stand by their prior arguments traversing the requirement. See prior response dated November 5, 2004. The Applicants remind the Examiner that the election of species is provisional and if no prior art against the elected species is found, the search of the Markush-type claim will be extended. M.P.E.P. § 803.02. For reasons discussed below, the cited references are not prior art against the present claims. Examination of the withdrawn claims is in order and is respectfully requested.

### **III. Claim objections**

Claim 67, 99-103, 108, 112, 114-117 and 121 were objected to for allegedly depending from a non-elected invention. However, claim 67 is not a dependent claim and was included in the original restriction requirement (Group I) set forth on page 2 of the Office action dated June 18, 2004. Accordingly, withdrawal of the objection of claim 67 is in order and is respectfully requested. Claims 99-103, 108, 112, 114-117 and 121 were cancelled and thus the objection is moot with respect to those claims.

#### **IV. Rejection under 35 U.S.C. § 112, second paragraph**

Claims 9 and 101(cancelled) were rejected for alleged ambiguity as to the term “substantially.” Claims 21 and 113 (cancelled) were also rejected for alleged ambiguity as to the term “sufficient.” Applicants respectfully traverse these rejections and submit that an ordinary skilled artisan would understand the meaning of these terms based on their everyday meaning. As shown in the attached excerpts taken from the 4<sup>th</sup> edition of the American Heritage Dictionary of the English Language (2000, Houghton Mifflin Co., Boston, MA, USA), which was available at the time the present application was filed, these terms have been defined and would be understood by the ordinary skilled artisan. For instance, “substantial” refers to a real (not imaginary) sustaining amount of material while “sufficient” means as much as needed. Accordingly, withdrawal of the § 112, second paragraph, against claims 9 and 21 is in order and is respectfully requested. The § 112, second paragraph, rejection against cancelled claims 101 and 113 is moot.

#### **V. Rejections under 35 U.S.C. § 103 based on Chu and Shultz**

Claims 1-3, 6-12, 16-28, 67-79, 94-95 (cancelled), 98-103(cancelled), 108-120 (cancelled) and 122-124 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu et al. U.S. Patent no. 6,174,704 (“Chu”) in view of Shultz U.S. Patent no. 6,242,235 (“Shultz”). The basis for the rejection is described on pages 7 and 8. Specifically, the Examiner alleged that it would have been obvious to add Tomah E-18-15 and/or Tomah E-18-5 based on Shultz’s teachings to Chu’s aqueous solutions containing octylthioglucosides. Applicants respectfully traverse this rejection.

The Federal Circuit reiterated the manner in which obviousness rejections are to be reviewed. Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, “a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.” *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991), citing *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5

U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988). Contrary to the Examiner's position, neither Chu nor Shultz, alone or in combination, teach or suggest what the Applicants have done.

Chu merely relates to a method for recovering proteins using a reagent solution consisting essentially of an alkylglycoside or alkylthioglycoside. See col. 1, lines 51-55. Contrary to the Examiner's position, Chu is completely silent with respect to a composition having "at least one surfactant having a hydrophobic-lipophilic balance value in the range from about 11 to about 16" and further in combination with "at least one cell membrane altering compound." See claims 1 and 67. A disclosure of a solution consisting essentially of alkylglycoside or alkylthioglycoside with added buffers and/or lysosyme is not a disclosure or suggestion of the composition and method as presently claimed. Shultz adds nothing that remedies the deficiencies in Chu's teachings.

Shultz relates to compositions for stabilizing proteins. Shultz does not suggest that detergents of any type in the HLB range of about 11-16 and is limited to cationic surfactants. There would be no incentive to select ANY surfactant in this HLB range in order to provide the composition or method of the present invention as presently claimed. For example, Triton W-30 is listed as a surfactant that does not stabilize the enzyme activity (see Shultz at Table 1, col. 9, about line 57). In contrast, this anionic surfactant was demonstrated to operate in the present invention (See example 3, page 30, line 28 (sample A)).

Selection of a material such as a surfactant to provide enzyme stability does not automatically presume that it will also provide effective lysis. Some surfactants can form micelles that may act to provide additional stabilization of cellular membrane proteins, thus making extraction more difficult. Accordingly, without a suggestion of lysis in Shultz, one of ordinary skill would not be motivated by Shultz's teachings concerning protein stabilization to include a surfactant (e.g., Tomah E-18-15 or E-18-5) in Chu's lysis reagent and thus arrive with the presently claimed invention with any reasonable expectation of success.

Accordingly, withdrawal of the § 103 rejection of the claims based on Shultz and Chu is in order and is respectfully requested.

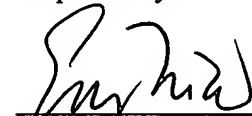
#### IV. Conclusion

In light of the above discussion and amendment, the Applicants submit that the claims are in allowable condition. A Notice to this effect is respectfully requested.

Reconsideration of this application is respectfully requested and a favorable determination is earnestly solicited. The Examiner is invited to contact the undersigned representative if the Examiner believes this would be helpful in expediting the allowance of this application.

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Respectfully submitted,



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